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EXAMINER	
DAVIS, M	
ART UNIT	**PAPER NUMBER**
1806	6

DATE MAILED: 09/09/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 (month(s)) or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-47 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 26-41, 45-47 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-47 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

– SEE OFFICE ACTION ON THE FOLLOWING PAGES –

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-25, drawn to an isolated nucleic acid molecule which specifically hybridizes under stringent conditions to a sequence of SEQ ID Nos: 2-12, 45 classified in class 536, subclass 23.1.

   II. Claims 26-41, 45-47, drawn to a method of screening for neoplastic cells, using as a probe a sequence of SEQ ID Nos: 1-12, 45, classified in class 435, subclass 6.

   III. Claims 42-43, 45-47, drawn to a method of screening for neoplastic cells, using as a probe an antibody against a polypeptide encoded by a sequence of SEQ ID Nos: 1-12, 45, classified in class 435, subclass 7.1.

   IV. Claim 44, drawn to a method of treating cancer, classified in class 514, subclass 44.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions (I) and (II-IV) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05 (h). In this instant case, a DNA sequence could be used for multiple purposes, e.g. for the

detection of similar DNA or RNA sequences, for making an expression vector, for producing its encoded protein, and for treating cancer.

The methods of Groups II-IV differ in the method objectives, method steps and parameters and in the reagents used. Groups II-III are drawn to a method of diagnosis of a disease, whereas group IV is drawn to a method of treating a disease. Diagnosis of a disease is not a therapeutic procedure and obviously differs in objectives from group IV. Diagnosis of diseases requires biochemical assays and reagents and protocols that are different than those used for treatment of diseases. The method of group II is different from the method of group III because in group II, a DNA sequence is used as a probe, whereas in group III, an antibody is used as a probe. Clearly the objectives and reagents used in the three methods are distinct and would require different searches in the commercial data bases, as well as the patent shoes.

Because these inventions are distinct for the reason given above and have acquired a separate status in the art as shown by their different classification, and because the searches for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

A telephone call was made to Kevin L. Bastian on August 15, 1997 to request an oral election to the above restriction requirement, and results in an election of group II, claims 26-41, and 45-47 without traverse.

Accordingly, claims 26-41, and 45-47 are examined in this instant application.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendement of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

REJECTION UNDER 35 USC 112, SECOND PARAGRAPH

Claims 26-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 is indefinite for the use of the language " a probe which hybridizes selectively to a target polynucleotide sequence" which does not set forth the metes and bounds of the patent protection desired. The conditions of hybridization should be written to obviate this rejection.

REJECTION UNDER 35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 26,and 45-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Zakut-Houri, R et al, 1983, Nature, 306: 594-597, Chader, GJ et al, WO 95/334480, or Okubo, K et al, WO 95/14772, or Morris, CM et al, 1991, Blood, 78(4): 1078-1084, or Beach, DH, WO 93/24514.

Claim 26 is drawn to a method of screening for neoplastic cells comprising contacting a sample from a human patient with a probe which hybridizes selectively to a target polynucleotide sequence comprising SEQ ID Nos. 1-12, and 45. Claim 26 reads on a probe of any zises, provided it hybridizes, under any hybridization conditions, to any of SEQ ID Nos 1-12, and 45. Claims 45-47 are drawn to a method of detecting cancer, comprising detecting the overexpression of a protein encoded in a 20q13 amplicon, wherein said encoded protein is ZABC1, or 1b1.

Zakut-Houri et al teach detection of a sequence for the cellular tumor antigen p53, which is 82% similar to the claimed SEQ No.1, amino acids 2994 to 3000.

Chader et al teach detection of a pigment epithelium-derived factor (PEDF) which is 90% similar to the claimed SEQ ID No. 6, amino acids 1532 to 1833. Chader et al also teach that PEDF is detectable in most tissues, cells types, and tumors (p.11).

Okubo et al teach identification of genes for diagnosing abnormal cells, wherein one of the sequence is 96% similar to the claimed SEQ ID No. 7, amino acids 752 to 1202.

Morris et al teach detection of a fusion gene in chronic myelogenous leukemia, which is 88% similar to the claimed SEQ ID No. 9, amino acids 7427 to 7708.

Beach et al teach detection of cyclin to predict whether cells are likely to undergo cell division at an abnormally high rate, i.e. cancerous (p.6). Said cyclin is 77% similar to the claimed SEQ ID No. 9, amino acids 9 to 293.

Thus the methods for detecting cancer taught by Zakut-Houri et al, or Chader et al, or Okubo et al, or Morris et al, or Beach et al are the same as the claimed methods because the probes taught by prior art would hybridize to the claimed SEQ ID Nos. 1, 6-7, and 9. Furthermore, since SEQ ID Nos. 1, 6-7, and 9, are DNA sequences encoding part of the protein ZABC1 or 1b1, therefore the methods taught by prior art would inherently detect the overexpression of said DNA sequences, and consequently the overexpression of the encoded proteins.

Tanner et al teach increased copy number at 20q13 in breast cancer.

Kallioniemi et al teach detection and mapping of amplified DNA sequences originating from 20q13 in breast cancer.

Thus the method of detection of breast cancer taught by Tanner et al, or Kallioniemi et al is the same as the claimed invention of claim 45.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Minh-Tam B. Davis whose telephone number is (703) 305-2008. The examiner can normally be reached on Monday-Friday from 8:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached on (703) 308-2731. The fax phone number for this Group is (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [**lila.feisee@uspto.gov**].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless **the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122.** This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0916.

Minh-Tam B. Davis

August 30, 1997

Toni R. Scheiner

TONI R. SCHEINER
PRIMARY EXAMINER
GROUP 1800